

## REMARKS

### Objection to Drawings

The drawings were objected to and corrected formal drawings were required. In addition, it was indicated that the description of Figure 7, Panels A and B should clearly indicate that there are two Figures, i.e., 7A and 7B and that reference to “yellow staining” is not shown.

Accordingly, submitted herewith, under separate transmittal are Formal Figures including full-tone photographs of Figures 1 and 7A and 7B. The structures described in the specification are clearly visible in the full-tone photographs. The specification has been amended herein to recite Figures 7A and 7B on page 19 and reference to the “yellow” staining has been deleted. It is respectfully submitted that in view of the above and the Formal Figures, this objection is avoided and should be withdrawn.

### Election/Restriction

Applicants again respectfully traverse the requirement with respect to election among Groups A-R to the extent that such election requires election among amino acids of SEQ ID NOS.: 2, 15, 16 and the amino acid sequence of HMW protein encoded by plasmid pJJ701. As detailed in their Response submitted on May 1, 2002, amino acids of SEQ ID NOS.: 2, 15, 16 and the amino acid of the HMW protein encoded by plasmid pJJ 701 are at least 95% identical. Hence, a search of one of these sequences necessarily encompasses a search of the others.

Merely to expedite prosecution and not in any way to acquire with this restriction requirement, all pending claims are directed to the elected subject matter. Applicants reserve all rights to prosecute non-elected subject matter in a continuation or divisional application. Applicants reserve rights to Petition the Commissioner regarding the restriction requirements.

### Objections to Claims

Claims 48-57 are currently pending and claims 48-49, 51-52 and 54 are amended herein.

Claims 48-52 and 54-67 are objected to as reciting an improper Markush Group. The Office Action alleges that the peptides lack common “structural features” which are “common to the essential utility.”

Attorney for Applicants note that election was made, with traverse, to the subject matter of Group I and Group A to the extent of methods of use of *Chlamydia* HMW protein

of SEQ ID NO: 2. Merely to expedite prosecution and not in any way to acquiesce with this objection, all pending claims are amended herein to be directed to this elected subject matter. Hence this objection is avoided and must be withdrawn.

Applicants note for the record, however, that they fully reserve all rights to Petition the Commissioner with respect to the restriction requirement among the polynucleotides of SEQ ID NOS.: 1, 15 and 16 (or polynucleotides encoding amino acids of SEQ ID NOS.: 2, 23 and 24) which restriction requirement has been made final and is related to the objections alleging an improper Markush group.

#### Rejection Under Section 112, 1<sup>st</sup> Paragraph

Claims 54-57 are rejected under Section 112, 1<sup>st</sup> paragraph as containing new matter with respect to the specific hybridization conditions recited.

Although not agreeing, attorneys for Applicants have amended independent claim 54 (and claims 55-57 dependent thereon) to recite, more particularly, stringent hybridization conditions comprising “50% formamide and 37°C.” Attention is directed, in particular, to the specification at page 28, lines 16-25, especially at lines 21-25 which states: “By way of example, . . . convenient hybridization temperatures in the presence of 50% formamide are: . . . 37°C for 90 to 95% homology . . . .”

Thus, there is specific written description support for the recited hybridization conditions.

Claims 54-57 are also rejected under Section 112, 1<sup>st</sup> paragraph. The Office Action indicates that “while the specification enables nucleic acids which hybridize to the complementary strand of SEQ ID NO.: 1 and encode peptides capable of similarly reacting with the peptide coding strand”, it does not provide enablement for “nucleic acids which hybridize to the coding strands”, because such would not encode peptides capable of reacting with antibody specific for a peptide of SEQ ID No.: 2.

Accordingly, attorneys for Applicants have amended independent claim 54 (and claims 55-57 dependent thereon) to recite the nucleic acids admitted to be enabled, i.e., nucleic acids which hybridize to the complement of SEQ ID NO.: 1 and encode a peptide recognized by an antibody that specifically binds to a peptide of amino acid of SEQ ID NO.: 2.

Hence, this rejection is avoided and must be withdrawn.

### Rejections Under Section 102

Claims 48-57 are rejected under Section 102(e) as anticipated by U.S. Patent No. 5,725,863 by (Daniels). The Office Action alleges that Daniels “teach[es] isolated *Chlamydia* polypeptides ranging from molecular weights 40 to 140 kDa isolated from *Chlamydia*.” The Office Action further allege that “The *Chlamydia* may be either *psittaci* or *trachomatis*” citing col. 4, lines 18-28 of Daniels.

Attorneys for Applicants respectfully, but emphatically, submit that this rejection is plainly wrong!

Firstly, with respect to present claims 48-50 and 51 and 54 (as well as claims 55-57 dependent thereon) as amended herein, it is pointed out that these claims are directed to methods of use of isolated *Chlamydia* HMW protein of *C. trachomatis*, *C. pecorum* or *C. pneumoniae*.

In complete contrast, the only organism mentioned in Daniels as a source of any *Chlamydia* protein is *C.psittaci*. Attention is directed to the teaching of Daniels at Col.1, lines 9-11; Col. 3. lines 34-39; Col. 3, lines 45-48; at Col. 4, lines 52-53; at Col. 6, lines 5-56; Col. 8, lines 24-25; Col. 8, line 45.

The portion of Daniels cited in the Office Action i.e., Col. 4, lines 18-28 also only refers to *C. psittaci* as a source of any protein. It reads:

The polypeptides of the present invention are capable of forming “neutralizing antibodies” i.e., antibodies that will protect against *Chlamydia psittaci* and *Chlamydia trachomatis* in a variety of animals.

Thus, it is clear, that contrary to the allegation in the Office Action, Daniels does not describe any protein isolated from any organism except *C. psittaci*. He only suggests that the polypeptides from *C. psittaci* are capable of inducing antibodies against *C. psittaci* and *C. trachomatis*, i.e., the polypeptide are capable of inducing cross-reactive antibody. No protein of *C. trachomatis*, much less any other *Chlamydia* species is suggested, must less disclosed, by Daniels.

Hence, this rejection cannot stand against claims 48-50 and 51 and 54 (as well as claims 55-57 dependent thereon).

Secondly, with respect to claims 52 and 53, it is respectfully pointed out that the *Chlamydia* HMW protein used in the methods of these claims is recombinantly obtained and comprises the full length of the HMW protein of SEQ ID No.: 2 including the first 28 amino acid residues which are missing from mature HMW protein isolated from *Chlamydia*. Hence,

Accordingly, it is submitted that the rejection must be withdrawn.

Claims 54-57 are also rejected under Section 102(e) as anticipated by U.S. Patent No. 5,849,306 to Sim (Sim). The Office Action indicates that Sim teaches nucleotides encoding *Plasmodium falciparum* proteins useful for vaccination against malaria. The Office Action further asserts that the nucleic acids of Sim, “in particular residues 4436-4416 of SEQ ID NO.: 11 shares 100% similarity with instant SEQ ID NO.: 1, residues 3470-3490 and thus encodes a 6mer of SEQ ID NO.: 2 which may be recognized by an antibody to SEQ ID NO.: 2”. The Office Action concludes that thus, Sim anticipates these claims.

Attorneys for Applicants respectfully, but emphatically, disagree and submit that the assertion that residues 4436- 4416 of SEQ ID NO.: 11 of Sim encode any portion of SEQ ID NO.: 2 is plainly wrong!

Firstly, it is noted that nucleotide residues 3470-3490 of present SEQ ID NO.: 1 do not encode any part of the HMW protein of the present invention having an amino acid sequence of SEQ ID NO.: 2. Residues 3470-3490 of present SEQ ID NO.: 1 are outside the coding region which codes for SEQ ID NO.: 2. This is clear from SEQ ID NO.: 1 of the present Substitute Sequence Listing submitted on May 1, 2002 which aligned the nucleotide and encoded amino acid sequences, a copy of SEQ ID NO.: 1 of which is attached for convenience.

Thus, even if any of the cited residues of Sim actually shared similarity with residues 3470-3490 of present SEQ ID NO.: 1, such residues would not encode any epitope of SEQ ID NO.: 2.

Secondly, as demonstrated below, residues 4436-4416 of SEQ ID NO.: 11 of Sim are not the same as residues 3470-3490 of present SEQ ID NO.: 1.

Present SEQ ID NO.: 1

5' 3'

tac atc att ttg ttt ttt ag

3470 3490

Residues 4436-1416 of Sim's SEQ ID NO.: 11

5'	3'
cta aaa aac aaa atg atg tag	
4416	4436

3'	5'
gat gta gta aaa caa aaa atc	
4436	4416

Comparison shows that neither of these sequences is identical to residues 3470-3490 of present SEQ ID NO.: 1.

Finally, as currently amended, claim 54 recites more particularly that the method uses a *Chlamydia* HMW protein encoded by a nucleic acid that hybridizes to the complement of the coding region of SEQ ID NO.: 1 (*i.e.*, from residue 382 to residue 3417 of SEQ ID NO.: 1) which encodes SEQ ID NO.: 2 and encodes a protein that is recognized by an antibody that binds specifically to a peptide comprising an amino acid sequence of SEQ ID NO.: 2. Such protein is nowhere taught in Sim.

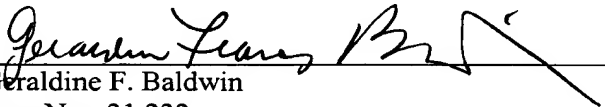
Hence, this rejection is in error and must be withdrawn.

In light of the above amendments and remarks, Applicants respectfully request that the Examiner reconsider this application with a view towards allowance. The Examiner is invited to call the undersigned attorney at (212)790-2296 if a telephone call could help resolve any remaining items.

Respectfully submitted,

**PENNIE & EDMONDS LLP**

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